MAR 27

K000060

01/06/00

SECTION 13 SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	SenoRx Inc.
b. Company Address:	13766 Alton Parkway, Suite 144 Irvine, CA 92618
c. Company Phone: Company Facsimile:	(949) 454-1300 (949) 454-1299
d. Contact Person:	Amy Boucly Director, Regulatory Affairs and Quality Assurance
e. Date Summary Prepared:	January 4, 1999

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	***Gel Mark™ Biopsy Site Marker***
b. Classification Name:	Implantable Staple 21 CFR 878.4750

3. IDENTIFICATION OF PREDICATE DEVICES

Company:	Ethicon Endo-Surgery, Inc.
Device:	MicroMark™ Clip
510(k) No.	K970817
Date Cleared:	September 11, 1997

4. DESCRIPTION OF THE DEVICE

The Gel Mark Biopsy Site Marker is a sterile, disposable device, which is intended for marking a biopsy site immediately following removal of tissue during percutaneous breast biopsy procedures.

The Gel Mark Biopsy Site Marker consists of a disposable syringe-type applicator containing dehydrated gelatin pellets and dehydrated gelatin pellets with embedded wire forms.

5. STATEMENT OF INTENDED USE

The Gel Mark device is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

6. SUBSTANTIAL EQUIVALENCE

The Gel Mark™ Biopsy Site Marker is substantially equivalent to the MicroMark Clip in that each device is comprised of an applicator which contains markers intended for the radiographic marking of breast tissue during percutaneous biopsy procedures. The markers are clearly visible radiographically.

7. BRIEF SUMMARY OF *IN VITRO* AND ANIMAL TESTS AND RESULTS

Design analysis and *in vitro* data confirm that basic functional characteristics are substantially equivalent to those of the predicate device. Testing included verification that the device meets intended specifications and performance requirements, including verification of applicator dimensional and functional specifications, and verification of radiographic visualization during simulated use testing and rabbit implant studies.

8. SUMMARY

The Gel Mark™ Biopsy Site Marker is substantially equivalent in intended use, overall design and technology and marker material to the MicroMark™ Clip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

Ms. Amy Boucly
Director Regulatory Affairs and Quality Assurance
Senorx, Inc.
13766 Alton Parkway, Suite 144
Irvine, California 92618

Re: K000060
Trade Name: Gel Mark Biopsy Site Marker
Regulatory Class: II
Product Code: GDW, FZP
Dated: January 6, 2000
Received: January 10, 2000

Dear Ms. Boucly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000060 01/06/00

2 FDA Indications for Use Page

510(k) number (if known): K000060

Device Name: **Gel Mark™ Biopsy Site Marker**

Indications for Use: **The Gel Mark™ Biopsy Site Marker is indicated for use to radiographically mark breast tissue during a percutaneous breast biopsy procedure.**

NPO for cmw

(Division Sign-Off)
Division of General Restorative Devices K000060
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)